Monitoring visit filing checklist

This list applies to both electronic and paper filing.

1. Email chain(s) to schedule monitoring visit. The correspondence should include:

    a. List of all documents required (including access to electronic systems)
    b. Members of staff they would like to meet during the meeting
    c. Arranging meeting with PI (at least every other visit)
    d. Arrangements with pharmacy and other support departments where required

2. Note to detail what documents have been reviewed prior to the visit. This can include:

    a. Previous monitoring visit report(s) (MVR) and/or audit report(s) (to ensure that previous findings have been closed).
    b. Any Serious Adverse Event (SAEs)/Suspected Unexpected Serious Adverse Reaction (SUSARs.)
    c. Monitoring plan (to assess compliance).
    d. Recent correspondence.
    e. Latest version of the protocol.
    f. Recent amendments.
    g. CRFs(if available).
    h. Status of site(e.g. recruiting, in follow-up).
    i. Recruitment at the site (if available, i.e. from the sponsor's database, previous monitoring reports).
    j. Minutes of study committee meetings and evidence of other critical decision-making.

3. Draft monitoring report

4. GCP manager review of report

5. Final signed version of report

6. Email sending report to site

    a. The PI must be included in this email

7. Response to findings from the study team

8. Email confirming acceptance of finding resolution

Additionally, the following may be required for some visits:

9. **If critical findings identified**: email escalating these to PI, CI, GCP manager and governance operations manager immediately.

10. **If study team are one week late in responding to findings:** Email to the GCP manager to escalate.

11. Any other pertinent correspondence